

### **Remarks**

The Office Action mailed January 6, 2004 has been received and reviewed. No claims having been added, canceled, or amended, the pending claims are claims 1-42, 44-45, and 53-65. Claims 1-38 having been withdrawn from consideration by the Examiner, the claims currently under examination are claims 39-42, 44-45, and 53-65.

The specification has been amended to update publication information for recited pending applications.

Reconsideration and withdrawal of the rejections are respectfully requested.

### **Objections to the Claims**

The Examiner objected to claims 55-63 under 37 C.F.R. §1.75(c), as being of improper dependent form for allegedly failing to further limit the subject matter of a previous claim. Specifically, the Examiner alleged that dependent claims 55-63 recite language directed to material tested in the devices, which would also be an intended use that would be given no patentable weight during examination. Applicants respectfully traverse the objection.

37 C.F.R. §1.75(c) states that “[o]ne or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application.”

Applicants respectfully submit that claims 55-63 refer back to and further limit claim 39 as required by 37 C.F.R. §1.75(c).

Specifically, claim 39 recites not only a volume for containing a biological sample mixture, but also that the device is operable to remove small negatively charged organic molecules from the biological sample mixture. Claims 55-63 recite further language directed to the biological sample mixture and/or the small negatively charged organic molecules. Thus, claims 55-63 refer back to and further limit language recited in claim 39 as required by 37 C.F.R. §1.75(c). Therefore, Applicants respectfully submit that claims 55-63 are in proper dependent form.

The Examiner further asserted that some of the language would be an intended use that would be given no patentable weight during examination. Applicants disagree that the language at issue is related to "an intended use." Moreover, Applicants respectfully submit that whether or not language in a claim is given patentable weight by the Examiner during examination is immaterial to the determination of proper claim form pursuant to 37 C.F.R. §1.75(c).

Based on the remarks presented herein above, Applicants respectfully submit that claims 55-63 are in proper dependent form. Reconsideration and withdrawal of the objection to the claims is respectfully requested.

#### **Provisional Obviousness-Type Double Patenting Rejections**

Claims 39-42, 44-45, and 54-63 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-61 of copending U.S. Application No. 10/417,609. Further, claims 39-42 and 54-63 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-53 of copending U.S. Application No. 10/027,226 in view of U.S. Pat. No. 6,344,326 (Nelson et al.). As previously indicated, upon an indication of otherwise allowable subject matter and in the event these rejections are maintained, Applicants will provide an appropriate response.

In the event that the provisional obviousness-type double patenting rejections are the only rejections remaining in the present application, the Examiner is respectfully requested to withdraw the provisional obviousness-type double patenting rejection and allow the present application to issue as a patent pursuant to M.P.E.P. §822.01.

### **Rejection under 35 U.S.C. §103**

The Examiner rejected claims 39-41, 44-45, and 53-65 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Nelson et al.) in view of U.S. Pat. No. 6,265,168 (Gjerde et al.). Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §706.02(j).

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

The Amendment and Response submitted by Applicants on October 3, 2003 included remarks (e.g., pages 19-21), which Applicants hereby incorporate by reference in the present response, arguing that both Nelson et al. and Gjerde et al. lack, among other things, a disclosure or suggestion of a device that includes a plurality of process arrays wherein at least one of the process arrays comprises a *surface* comprising *an anion exchange material partially coated with a negatively charged polymer* (e.g., present independent claim 39).

However, the Examiner characterized the arguments as "spurious," because "[a]pplicant has not specified in the claim that the *surface* must be negative" (page 6, paragraph 10 of the Office Action mailed January 6, 2004; emphasis in original). Applicants respectfully disagree with the Examiner's characterization as discussed herein below.

Claim 39 recites that at least one of the process arrays includes a *surface* comprising an anion exchange material *partially coated with a negatively charged polymer*. Thus, Applicants respectfully submit that it would be clear to one of skill in the art that part of the *surface* of one of the process arrays includes *a negatively charged polymer*, and that the Examiner's remarks are not supported by the present claim language. In the event that this rejection is maintained in the next Official Communication, clarification of the Examiner's remarks are respectfully requested.

Thus, Applicants respectfully reiterate that Nelson et al. and Gjerde et al. each fail to teach or suggest all the claim language, and that Nelson et al. in view of Gjerde et al. fail to provide Applicants' claimed invention. Moreover, Applicants respectfully submit that one of skill in the art would have no motivation to modify Nelson et al. in view of Gjerde et al. to arrive at the presently claimed invention.

Specifically, the present invention discloses a device that is operable to *remove small negatively charged organic molecules* from a biological sample mixture (e.g., independent claim 39). As described in the present specification, " 'removal' of unwanted molecules involves adhering such molecules to the solid-phase material and allowing desirable products to remain in solution. This is in contrast to conventional elution methods that involve adhering the desirable products to the solid-phase material, washing away the unwanted molecules, and eluting the desirable products to remove them from the solid-phase material." (Specification at page 4, lines 25-30).

In contrast to the present invention, Nelson et al. suggest the use of ion exchange resins as "[s]uitable capture media for proteins" (column 8, lines 16-18). In short, Nelson et al. suggest conventional elution methods that involve adhering the desirable products (e.g., proteins, column 8, lines 16-18) to the solid-phase material (e.g., ion exchange resins; column 8, lines 16-18), (i.e., "enrichment;" column 2, lines 53-57), washing away the unwanted molecules (e.g., "waste fluid flows away from said main electrophoretic flowpath through a discharge outlet;" Abstract), and eluting the desirable products to remove them from the solid-phase material (e.g., "subsequent movement through the main electrophoretic flowpath;" column 2, lines 57-58).

Similarly, in contrast to the present invention, Gjerde et al. disclose conventional elution methods that involve "[t]rapping the nucleic acid(s) of interest on the DNA Chromatography matrix under appropriate DNA Chromatography conditions [and] . . . [e]xposing the trapped nucleic acid(s) to chemical and/or thermal conditions which quantitatively release those components selected for removal" (column 29, lines 13-19).

Thus, Applicants respectfully submit that one of skill in the art would have no motivation to modify the teachings of Nelson et al. in view of Gjerde et al. to arrive at the presently claimed invention (e.g., independent claim 39). Moreover, Applicants respectfully submit that modification of Nelson et al. in view of Gjerde et al. from conventional elution methods to the presently claimed method, would change the principle of operation of the invention being modified, and therefore, the present claims are patentable over Nelson et al. in view of Gjerde et al. *See, for example*, M.P.E.P. §2143.01, which states that "[I]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."

The Examiner also rejected claim 42 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Nelson et al.) in view of U.S. Pat. No. 6,265,168 (Gjerde et al.) as applied above, and further in view of U.S. Pat. No. 6,319,469 (Mian et al.). Applicants respectfully traverse the rejection.

Claim 42 depends from independent claim 39. Applicants respectfully submit that Mian et al. provide nothing to correct the deficiencies of Nelson et al. in view of Gjerde et al. Thus, Applicants respectfully submit that claim 42 is patentable for at least the reasons presented herein above for the patentability of independent claim 39, in addition to the subject matter recited therein.

In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103.

**Request for Rejoinder**

Claims 1-38 recite methods of using a device as recited, for example, in claim 39. Specifically, independent claims 1-2, 17-18, 20-21, and 36 recite language from independent claim 39. Upon an indication of claim 39 being allowable, Applicants respectfully request that the method claims (e.g., claims 1-38) also be examined and passed on to allowance pursuant to M.P.E.P. §821.04. *See, for example, In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fec. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

Amendment and Response

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For: METHODS AND DEVICES FOR REMOVAL OF ORGANIC MOLECULES FROM BIOLOGICAL MIXTURES USING ANION EXCHANGE

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**Summary**

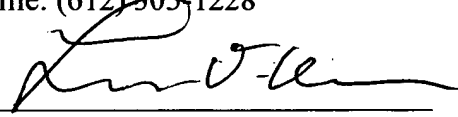
It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
PARTHASARATHY et al.

By  
Mueting, Raasch & Gebhardt, P.A.  
P.O. Box 581415  
Minneapolis, MN 55458-1415  
Phone: (612) 305-1220  
Facsimile: (612) 305-1228

May 6, 2004

Date

By:   
Loren D. Albin  
Reg. No. 37,763  
Direct Dial (612)305-1225

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**CERTIFICATE UNDER 37 CFR §1.10::**

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I hereby certify that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: 

Name: Rachel Gagliardi-Gabriele